REMARKS

Applicants appreciate the Examiner's thorough examination of the subject application and request reconsideration of the subject application based on the foregoing amendments and the following remarks.

Claims 1-37, 44, 46-63 and 74-89 are pending in the subject application. Claims 38-43 and 64-73 were previously canceled.

Claims 1, 37, 46-63 and 74-89 stand rejected under 35 U.S.C. §103. Claim 44 was objected to as depending from a rejected base claim; however, the Examiner indicated that this claim would be allowable if appropriately re-written in independent form. Claims 20 and related claims were objected to because of an identified informality.

The second numbered claim 20 appearing in the subject application was canceled in the foregoing amendment as it appears to be a duplicate of claim 21 as had been noted by the Examiner.

Claim 44 was written in independent form as suggested by the Examiner.

The claims 1, 52, 74 and 75 were amended for clarity and to more distinctly claim Applicant's invention as it relates to a system/ method for simulating the use of a medical device as well as simulating movement of the medical device after the medical device has been physically inserted into the simulated body cavity or lumen of a manikin. Claims 52, 74 and 75 also were amended to indicate that the simulated body cavity or lumen was within a simulacrum of a patient or a representation of the body of a patient such as a mankin. Claims 74 and 75 also

were amended to provide for the displaying of images corresponding to the simulated body cavity or lumen and the medical device therein.

Claims 2-37, 46-51, 53-63 and 76-89 were amended so as to be consistent with the language of the associated amended base claim as well as for consistency of language with an intervening claims and amongst the claims. In addition, claims were amended in the foregoing amendment, as needed, so as to be in better form, to address possible antecedent basis concerns and to correct typos.

Claims 7 and 8 also were amended to more clearly describe the tactile feedback mechanism and its responsiveness to simulated forces being exerted on the medical device within the simulated body cavity or lumen.

Claim 9 also was amended to more clearly describe the tracking device and also to provide that the system further includes a display on which is displayed images corresponding to the medical device and the simulated body cavity or lumen.

Claim 16 also was amended so this claim now depends from claim 9 instead of claim 10.

Claim 19 also was amended so this claim now depends from claim 1 instead of claim 18 and also so as to more clearly describe the relationship between functionalities of the system.

Claim 21 also was amended to clarify that the simulated image be displayed on the simulated scanning display also can be a reconstructed 3-D mage.

Claim 23 also was amended to indicate other imaging systems that can be simulated in the present invention.

Claims 28, 29 and 33 also were amended to more clearly describe the relationship between functionalities of the system as well as that the obtained images/ data can be displayed to the user.

The amendments to the claims are supported by the originally filed disclosure and thus, entry of these amendments into the subject application is respectfully requested.

35 U.S.C. §103 REJECTIONS

Claims 1-37, 46-63 and 74-89 stand rejected under 35 U.S.C. §103 as being unpatentable over the combination of Cai et al., Parametric Modeling Based on Multi-Layered Approach for Design and Validation of Catheterization Devices [citations omitted; "Cai"] in view of Chosack et al. [WO 99/38141; "Chosack"] alone or in combination with Rosenberg et al. [U.S. Patent 5,959,613; "Rosenberg"]; Belson, et al. [U.S. Patent 6,610,007; "Belson"]; Simon et al. [U.S. Patent 6,470,207; "Simon"] and Saunders [U.S. Patent 6,572,376]; Pollak, et al. [U.S. Patent 66,106,297; "Pollak"] and Issenberg, et al. Simulation Technology for Health Care Professional Skills Training and Assessment [citations omitted; "Issenberg"]; Pollak, et al. [U.S. Patent 6,106,297; "Pollak"] and Issenberg, et al. Simulation Technology for Health Care Professional Skills Training and Assessment [citations omitted; "Issenberg"] in further view of Hon [U.S. Patent 6,074,213]; or Merrill [U.S. Patent 6,106,301] for the reasons provided on pages 2-14 of the above-referenced Office Action. Because claims were amended in the foregoing amendment, the following discussion refers to the language of the amended claim(s). However, only those

amended features specifically relied on in the following discussion shall be considered as being made to overcome the prior art reference.

Applicants respectfully submit that the claims are patentable over the identified combination of Cai and Chosack, even when combined with the other cited art, as the combination of Cai and Chosack does not describe, teach or suggest a system for simulating the use and movement of a medical device. Applicants also respectfully disagree with the assertions in the Office Action that Cai discloses a system for simulating movement of a medical device that is disposed in a simulated cavity or lumen of a manikin. While Applicants believe that the pending claims are patentable over the cited art, in the interests of advancing prosecution Applicants amended the independent claims so as to more clearly provide that the claimed system/ method is a system/ method for simulating the use of a medical device as well as simulating movement of the medical device after the medical device has been physically inserted into the simulated body cavity or lumen and an interface device. The system and methods of the present invention are particularly adaptable for use in training a clinician in the use of medical devices (*e.g.*, training eye and hand coordination) as well as being useable for developing and/or testing procedures, devices and/ or techniques in advance of performing or using the procedure, device or technique on a real patient (*e.g.*, pre-treatment testing).

The article/ paper by Cai et al identified in the Office Action, is directed to CAD system entitled CathWorks that is useable to design and validate catheterization devices. An FEM engine is developed and embedded in CathWorks for the validation of the catheter design. The

article also briefly describes a process by which a *virtual* guidewire/catheter, presumably that for a guidewire/ catheter developed using CathWortks, is inserted into the femoral or brachial position of a *virtual* human vasculature and then navigated inside the blood vessels by a sequence of operations until the catheter reaches the region of the target arteries. In sum, what is being described in the article is an integrated software package or system by which one can design a catheter and validate the design using virtual human vasculature.

The simulator system of claim 1 is particular suited to allow a clinician or user to manipulate catheters and other medical devices (*e.g.*, stents, coils, etc.) in a realistic manner through the interface device while the computational engine generates, in real-time, the movement and action of the simulated devices responsive to such manipulation. The simulator system of claim 1 couples the interface device actions (hand) with the real-time movement of the device and thus relates back to the user forces imposed on the medical device during such manipulations. This is nowhere described or discussed in Cai.

As further provided in claims 9 and 19, for example, such a system further includes a mechanism for displaying an image of the simulated body cavity or lumen (*e.g.*, a 3-D modeled image of the patent's vascular anatomy obtained from reconstructed medical images acquired from X-Ray (Fluoroscopy, CT), MRI or possibly ultrasound imaging systems) as well as an image of the medical device. In the present invention, a manikin or other simulacrum can house the interface device, and the medical devices (*e.g.*, catheters guide wires etc,) can be inserted through a small opening in the manikin/simulacrum and then directly into the into the interface

device. The movement of the medical device, such as determined by the interface tracking device, is coupled to the 2-D and 3-D reconstructed images of patient blood vessels or lumens or cavities seen on the image monitors such that the real-time movements of the devices within the blood vessels, etc are also displayed on the monitors. Such a system is particularly suited for simulating hand-eye coordinated movements since the simulator system couples the interface device actions (hand) with the real-time movement of the device in the images as seen on the display, display device or monitor (eye).

In sum, Cai does not describe or teach anywhere a system or methodology in which a medical device is physically inserted into an interface device and a simulated body cavity or lumen that is contained within an artificial body or simulacrum such as a manikin for used in simulating the use and movement of such a medical device. It necessarily follows that there also is no teaching or suggestion in Cai to modify the system and methodology described therein so as to yield a system and methodology in which a medical device is physically inserted into a simulated body cavity or lumen that is contained within an artificial body such as a manikin for used in simulating the use and movement of such a medical device.

Further, Cai does not describe or teach anywhere a system or methodology in which the movement of the medical device within a simulated cavity/ lumen in a manikin is modeled such that the interactions arising between the medical device and the simulated body cavity/ lumen are modeled and forces arising from such interactions are computed. Moreover, Cai does not describe or teach generating signals based on the computed forces that can be utilized to control

an active directional force feedback mechanism/ device thereby feeding back the computed forces to the user via the medical device.

This should not be surprising as Cai is a CAD based system for designing and validating the design of a catheter, and not a system or methodology in which a medical device is physically moved by a user or for simulating such a use of the medical device within a simulated cavity/lumen. In other words, the function(s) being carried out by the system and method of the present invention is not related at all to intended purpose and function of the CathWorks software described in Cai. Furthermore, it is respectfully submitted that if the system and method disclosed in Cai was modified so as to be capable of carrying out the functions and purposes of the present invention, the so modified device would be totally and completely unable to carry out the intended purpose and function of the CathWorks software described in Cai.

Moreover as to claims 9 and 19, these claims further provide that the movements of the medical device and the simulated body cavity or lumen are displayed on a display/display device/monitor. In this way, the clinician or first user can observe in real-time, the movement of the medical device with respect to the simulated body cavity or lumen responsive to the clinician's or user's actual manipulation of the inserted medical device. In addition to this not being described or discussed anywhere in Cai, it is respectfully submitted that if the system and method disclosed in Cai was modified so as to be capable of carrying out these functions, the so modified device would be totally and completely unable to carry out the intended purpose and function of the CathWorks software described in Cai.

As to the secondary reference, Chosack, this is being used for the limited purpose of providing the disclosure and teachings that are acknowledged as missing from the primary reference. Chosack does not anywhere provide any teaching or suggestion to destroy the functionality of the CAD software program described in Cai so as to yield a system that simulates use *and* movement of the medical device. While it is true that Chosack might suggest that the use of a manikin might enhance the simulation from the standpoint of training, this does not correspond to a teaching to take the CathWorks CAD program, that has to do with design and validation of catheterization device designs, and destroying this capability so the resultant can be used as a platform for establishing a training regime relating to the use of a medical device.

Applicants also make the following further observations as to the above noted combination of Cai and Chosack with the other above-identified references. The following, however, shall be considered as being at least the reason why the claimed invention is considered as being patentable over the cited art. The following shall not be construed as an admission that there are no other reasons why the claims are patenable over the cited art.

As also previously indicated by Applicants, Chosack does not suggest the use of physically based modeling embodying finite element methods. Although using animation to mimic certain processes such as blood flow and deformation, Chosack does not use a physically based finite element modeling system that calculates the amount of force that would be exerted as a result of interactions between a medical device and body cavity or lumen to provide force feedback to a user of the simulation system in addition to visual feedback; Chosack merely

describes providing real-time visual feedback. Further, Chosack does not describe altering the parameters of a finite element model of a device or body cavity or lumen in response to a user's interactions with the device.

As also previously indicated by Applicants, in contrast to the present invention the secondary reference, Rosenberg, describes and teaches a method and apparatus for shaping force signals (*i.e.*, an impluse-shaped forece singal) for a force feedback mechansim. Thus, the tertiary reference does not remedy the deficiency of the combination of Cai and Chosack and therefore the references combined do not disclose or suggest the present invention.

As also previously indicated by Applicants, Belson does not teach the use of physically based finite element modeling. Further, Belson does not disclose the use of perpendicular sensors nor provide any motivation to use such sensors. Thus, this tertiary reference does not remedy the deficiency of the combination of Cai and Chosack and therefore the references combined do not disclose or suggest the invention.

As also previously indicated by Applicants, Simon and Saunders do not teach the use of physically based finite element modeling. This tertiary combination of references does not remedy the deficiency of the combination of Cai and Chosack and therefore the references combined do not disclose or suggest the invention.

As previously indicated by Applicants, Pollak does not teach the use of physically based finite element modeling. As such, does not remedy the deficiency of the combination of Cai and Chosack and therefore the references, even if, combined do not disclose or suggest the invention.

As previously indicated by Applicants, Merril does not teach the use of physically based finite element modeling. Thus, the tertiary reference, Merril, does not remedy the deficiency of the combination of Cai and Chosack and therefore the references combined do not disclose or suggest the invention.

As provided in MPEP 2143.01, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F. 2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F. 2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). As provided above, the references cited, alone or in combination, include no such teaching, suggestion or motivation.

Furthermore, and as provided in MPEP 2143.02, a prior art reference can be combined or modified to reject claims as obvious as long as there is a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 19866). Additionally, it also has been held that if the proposed modification or combination would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. Further, and as provided in MPEP-2143, the teaching or suggestion to make the claimed combination and the reasonable suggestion of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). As can be seen from the forgoing discussion regarding

the disclosures of the cited references, there is no reasonable expectation of success provided in the reference(s). Also, it is clear from the foregoing discussion that the modification suggested by the Examiner would change the principle of operation of the device disclosed in the principal reference.

As provided by the Federal circuit, a 35 U.S.C. §103 rejection based upon a modification of a reference that destroys the intent, purpose or function of the invention disclosed in a reference, is not proper and the prima facie case of obviousness cannot be properly made. In short there would be no technological motivation for engaging in the modification or change. To the contrary, there would be a disincentive. *In re Gordon*, 733 F. 2d 900, 221 USPQ 1125 (Fed. Cir. 1984). In the present case it is clear that if the cited reference was modified in the manner suggested by the Examiner it would destroy the intent, purpose or function of the device as taught by the reference.

Although a prior art device "may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so." *In re Mills* , 916 F. 2d, 680, 682; 16 USPQ 2d 1430, 1432 (Fed. Cir. 1990). As the Federal circuit also has stated, "[t]he mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." *In re Fritch*, 972 F.2d 1260,1266, 23 USPQ2d 1780, 1783-84 (Fed. Cir. 1992). Obviousness may not be established using hindsight or in view of the teachings or suggestions of the inventor. *Para-Ordance Mfg. v. SGS Importers Int'l, Inc.*, 73 F.2d 1085, 1087, 37 USPQ2d 1237, 1239 (Fed. Cir. 1995).

It is respectfully submitted that for the foregoing reasons, claims 1-37, 46-63 and 74-89 are patentable over the cited reference(s) and thus, satisfy the requirements of 35 U.S.C. §103. As such, these claims are allowable.

CLAIM 44

In the above-referenced Office Action, claim 44 was objected to as being dependent upon a rejected base claim. It also was provided in the above-referenced Office Action, however, that this claim would be allowable if rewritten in independent form to include all the limitations of the base claim and any intervening claim(s).

Claim 44 was re-written in the foregoing amendment so as to be in independent form and to include all the limitations of the base claim there being no intervening claim(s). Accordingly, claim 44 is considered to be in allowable form.

CLAIM 20

In the above-referenced Office Action, claim 20 was objected to because there were two claims that were numbered as claim 20. It was further asserted that because of this, all the subsequently numbered claims would appear to be miss-numbered.

Applicants canceled the second numbered claim 20 from the subject application, as it appears to be a duplicate of the claim that is numbered claim 21. Also, the claims that depended from claim 20, were depending from the first numbered claim 20 and not from the limitations set

forth in the second numbered claim 20. Thus, the claims numbered claim 21 and higher are not miss-numbered nor do they need to be amended with the cancellation of the second numbered claim 20.

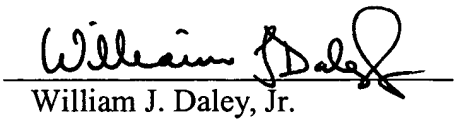
It is respectfully submitted that the above-identified informality has been corrected and the claims thus otherwise satisfy applicable patent laws, rules and/ or regulations.

It is respectfully submitted that the subject application is in a condition for allowance. Early and favorable action is requested.

Because the total number of claims and/or the total number of independent claims post amendment now exceed the highest number previously paid for, authorization is herewith to charge the required additional fees to the deposit account. However, if for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, the Commissioner is hereby authorized and requested to charge Deposit Account No. **04-1105**.

Respectfully submitted,
Edwards & Angell, LLP

Date: April 27. 2005

By: 

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